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| APPLICATION NO. | FII | LING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|------------|---------------|-------------------------|---------------------|------------------|
| 10/772,101 | 02/04/2004 | | Jacques Seguin | CVALVE.006CP1 6184 | |
| 20995 | 7590 | 03/31/2006 | | EXAMINER | |
| KNOBBE I | | IS OLSON & BE | GHERBI, SUZETTE JAIME J | | |
| FOURTEEN | | R | ART UNIT | PAPER NUMBER | |
| IRVINE, C | A 92614 | | | 3738 | |

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | | |
|--|---|-----------------------------------|--|--|--|--|--|
| Office Action Occurred | 10/772,101 | SEGUIN ET AL. | | | | | |
| Office Action Summary | Examiner | Art Unit | | | | | |
| | Suzette J. Gherbi | 3738 | | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the co | orrespondence address | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | |
| Status | | | | | | | |
| 1) Responsive to communication(s) filed on 13 Ma | Responsive to communication(s) filed on 13 March 2006. | | | | | | |
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| , | , — | | | | | | |
| . — | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | | |
| 4)⊠ Claim(s) <u>1-78</u> is/are pending in the application. | | | | | | | |
| , | 4a) Of the above claim(s) <u>10,17-30,46-74 and 76-78</u> is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | | |
| <u> </u> |)⊠ Claim(s) <u>1-4,6-9,11-16,31-36,38-44 and 75</u> is/are rejected. | | | | | | |
| 7)⊠ Claim(s) <u>5,35,37 and 45</u> is/are objected to. | | | | | | | |
| <u> </u> | election requirement | | | | | | |
| , — · · · · · · · · · · · · · · · · · · | | | | | | | |
| Application Papers | | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | | |
| 10)⊠ The drawing(s) filed on <u>2/2/04 & 6/17/04</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner. | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | | |
| 12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a)□ All b)□ Some * c)⊠ None of: | | | | | | | |
| Certified copies of the priority documents | Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| Certified copies of the priority documents | | | | | | | |
| Copies of the certified copies of the prior | | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| | | | | | | | |
| Attachment(s) | | | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/19/04. | Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other: | te atent Application (PTO-152) | | | | | |
| | | | | | | | |

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DETAILED ACTION

Election/Restrictions

- 1. Applicant's election without traverse of Species B(i) claims **1-9**, **11-16**, **31-45**, and **75** in the reply filed on 3/13/06 is acknowledged. Claims **1-9**, **11-16**, **31-45**, and **75** are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species there being no generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/13/06.
- 2. In the office action dated 1/9/06, two additional groups should have been added to species requirement.
- C(i) Figures 72a-72c
- D(i) Figures 73a-73e
- E(i) Figures 74a-75b
- 3. Applicant has elected species B(i) and states that claims 1, 31, 75 are generic to species U, V, W and X and request consideration of these species with the elected claims. The examiner has reviewed the application and will include these species (U, V, W and X) with the generic claims 1, 31, and 75.

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Priority

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4. This application repeats a substantial portion of prior Application No. 10/130,355 (now Patent 6,830,584), filed 11/15/00, and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it constitutes a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

- 5. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).
- 6. The disclosure of the prior-filed application, Application No. 10/130,355, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. In particular there is no support for newly added figures 13-75 in the parent application. Therefore the filing date for the instant application will be the date of filing **2/4/04**.

7. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in France on 5/25/01. It is noted, however, that applicant has not filed a certified copy of the foreign application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112

- 8. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 9. Claims 1-9, 11-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 10. Claim 1 recites the limitations "the base" and "the commisure points. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.



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12. Claim 75 is rejected under 35 U.S.C. 102(b) as being anticipated by Leonhardt et

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al. 5,957,949. Leonhardt et al. discloses the invention as currently claimed noting figure

4 comprising: a prosthetic valve assembly configured to replace a deficient native valve

with a non-cylindrical valve support (26) and at leasttone anchor (the stent ends that

flare serve as the anchor.

13. Claims 1-4, 7, 11-15, 31-34, 36, 38-44 are rejected under 35 U.S.C. 102(b) as

being anticipated by Shaolian et al. 6,299,637. Shaolian et al. discloses the invention

as claimed noting figures 1-4 and 11 comprising: a valve (42 col. 5, lines 1) having a

plurality of resilient leaflets; a valve support (52) with first (50) and second portions (54)

configured to collapse for delivery; and a radial restraint (46, see col. 6, lines 31-32 for

controlling a diameter of the second portion). The intended use recitation/functional

language of the claims carries no patentabale weight in the absence of any

distinguishing structure. Shaolian et al. clearly discloses the structure as claimed and is

found to be inherently capable of performing the function.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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15. Claims 6, 8-9, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaolian et al. in view of Kocur 6,350,277. Shaolian et al. has been disclosed however the restraining member does not specify a thread. Kocur teaches that endoprosthesis of various types may be deployed by utilizing restraining materials including threads (see figures 4a, 5a-6c, 7 and 8) which can surround the device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the device of Shaolian et al. and utilize the restraining devices as taught by Kocur because both devices scaffolds are made from self-expandable materials such as nitinol and are capable of being contracted with the restraints.

Allowable Subject Matter

- 16. Claims 5, 35, 37, 45 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- 17. Claim 16 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

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18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J-J Gherbi whose work schedule is Maxi-Flex off every other Friday and whose telephone number is 571-272-4751.

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- 19. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.
- 20. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.
- 21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suzette J-J Gherbi 28 March 2006

